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H. R. 3684

To amend the Federal Food, Drug, and Cosmetic Act to establish labeling requirements with respect to allergenic substances in foods, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 8, 2003

Mrs. LOWEY (for herself, Mr. GREENWOOD, Mr. LATOURETTE, Ms. WOOLSEY, Mr. SERRANO, Mr. PALLONE, Mr. HOEFFEL, Ms. SLAUGHTER, Mr. HINCHEY, Ms. NORTON, Ms. DELAURO, Mr. GEORGE MILLER of California, Mr. BROWN of Ohio, Ms. ROYBAL-ALLARD, and Mr. WAXMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish labeling requirements with respect to allergenic substances in foods, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Food Allergen Label-
5 ing and Consumer Protection Act of 2003”.

6 **SEC. 2. FINDINGS.**

7 Congress finds that—

1 (1) it is estimated that—

2 (A) approximately 2 percent of adults and
3 about 5 percent of infants and young children
4 in the United States suffer from food allergies;
5 and

6 (B) each year, roughly 30,000 individuals
7 require emergency room treatment and 150 in-
8 dividuals die because of allergic reactions to
9 food;

10 (2)(A) eight major foods or food groups—milk,
11 eggs, fish, Crustacean shellfish, tree nuts, peanuts,
12 wheat, and soybeans—account for 90 percent of
13 food allergies;

14 (B) at present, there is no cure for food aller-
15 gies; and

16 (C) a food allergic consumer must avoid the
17 food to which the consumer is allergic;

18 (3)(A) in a review of the foods of randomly se-
19 lected manufacturers of baked goods, ice cream, and
20 candy in Minnesota and Wisconsin in 1999, the
21 Food and Drug Administration found that 25 per-
22 cent of sampled foods failed to list peanuts or eggs
23 as ingredients on the food labels; and

1 (B) nationally, the number of recalls because of
2 unlabeled allergens rose to 121 in 2000 from about
3 35 a decade earlier;

4 (4) a recent study shows that many parents of
5 children with a food allergy were unable to correctly
6 identify in each of several food labels the ingredients
7 derived from major food allergens;

8 (5)(A) ingredients in foods must be listed by
9 their “common or usual name”;

10 (B) in some cases, the common or usual name
11 of an ingredient may be unfamiliar to consumers,
12 and many consumers may not realize the ingredient
13 is derived from, or contains, a major food allergen;
14 and

15 (C) in other cases, the ingredients may be de-
16 clared as a class, including spices, flavorings, and
17 certain colorings, or are exempt from the ingredient
18 labeling requirements, such as incidental additives;
19 and

20 (6)(A) celiac disease is an immune-mediated
21 disease that causes damage to the gastrointestinal
22 tract, central nervous system, and other organs;

23 (B) the current recommended treatment is
24 avoidance of glutens in foods that are associated
25 with celiac disease; and

1 (C) a multicenter, multiyear study estimated
2 that the prevalence of celiac disease in the United
3 States is 0.5 to 1 percent of the general population.

4 **SEC. 3. FOOD LABELING; REQUIREMENT OF INFORMATION**
5 **REGARDING ALLERGENIC SUBSTANCES.**

6 (a) IN GENERAL.—Section 403 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 343) is amended by
8 adding at the end the following:

9 “(w)(1) If it is not a raw agricultural commodity and
10 it is, or it contains an ingredient that bears or contains,
11 a major food allergen, unless either—

12 “(A) the word ‘Contains’, followed by the name
13 of the food source from which the major food aller-
14 gen is derived, is printed immediately after or is ad-
15 jacent to the list of ingredients (in a type size no
16 smaller than the type size used in the list of ingredi-
17 ents) required under subsections (g) and (i); or

18 “(B) the common or usual name of the major
19 food allergen in the list of ingredients required
20 under subsections (g) and (i) is followed in paren-
21 theses by the name of the food source from which
22 the major food allergen is derived, except that the
23 name of the food source is not required when—

1 “(i) the common or usual name of the in-
2 gredient uses the name of the food source from
3 which the major food allergen is derived; or

4 “(ii) the name of the food source from
5 which the major food allergen is derived ap-
6 pears elsewhere in the ingredient list, unless the
7 name of the food source appears elsewhere in
8 the ingredient list only in the common or usual
9 name of foods that are food ingredients that are
10 not major food allergens under section
11 201(qq)(2)(A) or (B).

12 “(2) As used in this subsection, the term ‘name of
13 the food source from which the major food allergen is de-
14 rived’ means the name described in section 201(qq)(1);
15 provided that in the case of a tree nut, fish, or Crustacean
16 shellfish, the term ‘name of the food source from which
17 the major food allergen is derived’ means the name of the
18 specific type of nut or species of fish or Crustacean shell-
19 fish.

20 “(3) The information required under this subsection
21 may appear in labeling in lieu of appearing on the label
22 only if the Secretary finds that such other labeling is suffi-
23 cient to protect the public health. A finding by the Sec-
24 retary under this paragraph (including any change in an

1 earlier finding under this paragraph) is effective upon
2 publication in the Federal Register as a notice.

3 “(4) Notwithstanding subsection (g), (i), or (k), or
4 any other law, a flavoring, coloring, or incidental additive
5 that is, or that bears or contains, a major food allergen
6 shall be subject to the labeling requirements of this sub-
7 section.

8 “(5) The Secretary may by regulation modify the re-
9 quirements of subparagraph (A) or (B) of paragraph (1),
10 or eliminate either the requirement of subparagraph (A)
11 or the requirements of subparagraph (B) of paragraph
12 (1), if the Secretary determines that the modification or
13 elimination of the requirement of subparagraph (A) or the
14 requirements of subparagraph (B) is necessary to protect
15 the public health.

16 “(6)(A) Any person may petition the Secretary to ex-
17 empt a food ingredient described in section 201(qq)(2)
18 from the allergen labeling requirements of this subsection.

19 “(B) The Secretary shall approve or deny such peti-
20 tion within 180 days of receipt of the petition or the peti-
21 tion shall be deemed denied, unless an extension of time
22 is mutually agreed upon by the Secretary and the peti-
23 tioner.

24 “(C) The burden shall be on the petitioner to provide
25 scientific evidence (including the analytical method used

1 to produce the evidence) that demonstrates that such food
2 ingredient, as derived by the method specified in the peti-
3 tion, does not cause an allergic response that poses a risk
4 to human health.

5 “(D) A determination regarding a petition under this
6 paragraph shall constitute final agency action.

7 “(E) The Secretary shall promptly post to a public
8 site all petitions received under this paragraph within 14
9 days of receipt and the Secretary shall promptly post the
10 Secretary’s response to each.

11 “(7)(A) A person need not file a petition under para-
12 graph (6) to exempt a food ingredient described in section
13 201(qq)(2) from the allergen labeling requirements of this
14 subsection, if the person files with the Secretary a notifica-
15 tion containing—

16 “(i) scientific evidence (including the analytical
17 method used) that demonstrates that the food ingre-
18 dient (as derived by the method specified in the noti-
19 fication, where applicable) does not contain aller-
20 genic protein; or

21 “(ii) a determination by the Secretary that the
22 ingredient does not cause an allergic response that
23 poses a risk to human health under a premarket ap-
24 proval or notification program under section 409.

1 “(B) The food ingredient may be introduced or deliv-
2 ered for introduction into interstate commerce as a food
3 ingredient that is not a major food allergen 90 days after
4 the date of receipt of the notification by the Secretary,
5 unless the Secretary determines within the 90-day period
6 that the notification does not meet the requirements of
7 this paragraph, or there is insufficient scientific evidence
8 to determine that the food ingredient does not contain al-
9 lergenic protein or does not cause an allergenic response
10 that poses a risk to human health.

11 “(C) The Secretary shall promptly post to a public
12 site a list of all notifications received under this subpara-
13 graph within 14 days of receipt and promptly post any
14 objections thereto by the Secretary.

15 “(x) Notwithstanding subsection (g), (i), or (k), or
16 any other law, a spice, flavoring, coloring, or incidental
17 additive that is, or that bears or contains, a food allergen
18 (other than a major food allergen), as determined by the
19 Secretary by regulation, shall be disclosed in a manner
20 specified by the Secretary by regulation.”.

21 (b) EFFECT ON OTHER AUTHORITY.—The amend-
22 ments made by this section that require a label or labeling
23 for major food allergens do not alter the authority of the
24 Secretary of Health and Human Services under the Fed-

1 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
2 seq.) to require a label or labeling for other food allergens.

3 (c) CONFORMING AMENDMENTS.—

4 (1) Section 201 of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 321) (as amended by sec-
6 tion 2(b)) is amended by adding at the end the fol-
7 lowing:

8 “(qq) The term ‘major food allergen’ means any of
9 the following:

10 “(1) Milk, egg, fish (e.g., bass, flounder, or
11 cod), Crustacean shellfish (e.g., crab, lobster, or
12 shrimp), tree nuts (e.g., almonds, pecans, or wal-
13 nuts), wheat, peanuts, and soybeans.

14 “(2) A food ingredient that contains protein de-
15 rived from a food specified in paragraph (1), except
16 the following:

17 “(A) Any highly refined oil derived from a
18 food specified in paragraph (1) and any ingre-
19 dient derived from such highly refined oil.

20 “(B) A food ingredient that is exempt
21 under paragraph (6) or (7) of section 403(w).”.

22 (2) Section 403A(a)(2) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 343–1(a)(2)) is
24 amended by striking “or 403(i)(2)” and inserting
25 “403(i)(2), 403(w), or 403(x)”.

1 (d) EFFECTIVE DATE.—The amendments made by
2 this section shall apply to any food that is labeled on or
3 after January 1, 2006.

4 **SEC. 4. REPORT ON FOOD ALLERGENS.**

5 Not later than 18 months after the date of enactment
6 of this Act, the Secretary of Health and Human Services
7 (in this section referred to as the “Secretary”) shall sub-
8 mit to the Committee on Health, Education, Labor, and
9 Pensions of the Senate and the Committee on Energy and
10 Commerce of the House of Representatives a report
11 that—

12 (1)(A) analyzes—

13 (i) the ways in which foods, during manu-
14 facturing and processing, are unintentionally
15 contaminated with major food allergens, includ-
16 ing contamination caused by the use by manu-
17 facturers of the same production line to produce
18 both products for which major food allergens
19 are intentional ingredients and products for
20 which major food allergens are not intentional
21 ingredients; and

22 (ii) the ways in which foods produced on
23 dedicated production lines are unintentionally
24 contaminated with major food allergens; and

1 (B) estimates how common the practices de-
2 scribed in subparagraph (A) are in the food indus-
3 try, with breakdowns by food type as appropriate;

4 (2) advises whether good manufacturing prac-
5 tices or other methods can be used to reduce or
6 eliminate cross-contact of foods with the major food
7 allergens;

8 (3) describes—

9 (A) the various types of advisory labeling
10 (such as labeling that uses the words “may con-
11 tain”) used by food producers;

12 (B) the conditions of manufacture of food
13 that are associated with the various types of ad-
14 visory labeling; and

15 (C) the extent to which advisory labels are
16 being used on food products;

17 (4) describes how consumers with food allergies
18 or the caretakers of consumers would prefer that in-
19 formation about the risk of cross-contact be commu-
20 nicated on food labels as determined by using appro-
21 priate survey mechanisms;

22 (5) states the number of inspections of food
23 manufacturing and processing facilities conducted in
24 the previous 2 years and describes—

1 (A) the number of facilities and food labels
2 that were found to be in compliance or out of
3 compliance with respect to cross-contact of
4 foods with residues of major food allergens and
5 the proper labeling of major food allergens;

6 (B) the nature of the violations found; and

7 (C) the number of voluntary recalls, and
8 their classifications, of foods containing
9 undeclared major food allergens; and

10 (6) assesses the extent to which the Secretary
11 and the food industry have effectively addressed
12 cross-contact issues.

13 **SEC. 5. INSPECTIONS RELATING TO FOOD ALLERGENS.**

14 The Secretary of Health and Human Services shall
15 conduct inspections consistent with the authority under
16 section 704 of the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 374) of facilities in which foods are manufac-
18 tured, processed, packed, or held—

19 (1) to ensure that the entities operating the fa-
20 cilities comply with practices to reduce or eliminate
21 cross-contact of a food with residues of major food
22 allergens that are not intentional ingredients of the
23 food; and

24 (2) to ensure that major food allergens are
25 properly labeled on foods.

1 **SEC. 6. GLUTEN LABELING.**

2 Not later than 2 years after the date of enactment
3 of this Act, the Secretary of Health and Human Services,
4 in consultation with appropriate experts and stakeholders,
5 shall issue a proposed rule to define, and permit use of,
6 the term “gluten-free” on the labeling of foods. Not later
7 than 4 years after the date of enactment of this Act, the
8 Secretary shall issue a final rule to define, and permit use
9 of, the term “gluten-free” on the labeling of foods.

10 **SEC. 7. IMPROVEMENT AND PUBLICATION OF DATA ON**
11 **FOOD-RELATED ALLERGIC RESPONSES.**

12 (a) IN GENERAL.—The Secretary of Health and
13 Human Services, acting through the Director of the Cen-
14 ters for Disease Control and Prevention and in consulta-
15 tion with the Commissioner of Food and Drugs, shall im-
16 prove (including by educating physicians and other health
17 care providers) the collection of, and publish as it becomes
18 available, national data on—

- 19 (1) the prevalence of food allergies;
20 (2) the incidence of clinically significant or seri-
21 ous adverse events related to food allergies; and
22 (3) the use of different modes of treatment for
23 and prevention of allergic responses to foods.

24 (b) AUTHORIZATION OF APPROPRIATIONS.—For the
25 purpose of carrying out this section, there are authorized
26 to be appropriated such sums as may be necessary.

1 **SEC. 8. FOOD ALLERGIES RESEARCH.**

2 (a) IN GENERAL.—The Secretary of Health and
3 Human Services, acting through the Director of the Na-
4 tional Institutes of Health, shall convene an ad hoc panel
5 of nationally recognized experts in allergy and immunology
6 to review current basic and clinical research efforts related
7 to food allergies.

8 (b) RECOMMENDATIONS.—Not later than 1 year
9 after the date of enactment of this Act, the panel shall
10 make recommendations to the Secretary for enhancing
11 and coordinating research activities concerning food aller-
12 gies, which the Secretary shall make public.

13 **SEC. 9. FOOD ALLERGENS IN THE FOOD CODE.**

14 The Secretary of Health and Human Services shall,
15 in the Conference for Food Protection, as part of its ef-
16 forts to encourage cooperative activities between the
17 States under section 311 of the Public Health Service Act
18 (42 U.S.C. 243), pursue revision of the Food Code to pro-
19 vide guidelines for preparing allergen-free foods in food
20 establishments, including in restaurants, grocery store
21 delicatessens and bakeries, and elementary and secondary
22 school cafeterias. The Secretary shall consider guidelines
23 and recommendations developed by public and private en-
24 tities for public and private food establishments for pre-
25 paring allergen-free foods in pursuing this revision.

1 **SEC. 10. RECOMMENDATIONS REGARDING RESPONDING TO**
2 **FOOD-RELATED ALLERGIC RESPONSES**

3 The Secretary of Health and Human Services shall,
4 in providing technical assistance relating to trauma care
5 and emergency medical services to State and local agencies
6 under section 1202(b)(3) of the Public Health Service Act
7 (42 U.S.C. 300d–2(b)(3)), include technical assistance re-
8 lating to the use of different modes of treatment for and
9 prevention of allergic responses to foods.

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